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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/341,196	07/06/1999	SUNITA DESOUZA	1103326-0571	4864

7470 7590 09/16/2002

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PATENT DEPARTMENT
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EXAMINER

GABEL, GAILENE

ART UNIT	PAPER NUMBER
1641	13

DATE MAILED: 09/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/341,196	Applicant(s) DESOUSA ET AL.
	Examiner Gailene R. Gabel	Art Unit 1641
<p><u>-The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</u></p> <p>THE REPLY FILED 10 July 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.</p>		
<u>PERIOD FOR REPLY [check either a) or b])</u>		
<p>a) <input type="checkbox"/> The period for reply expires _____ months from the mailing date of the final rejection.</p> <p>b) <input type="checkbox"/> The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.</p> <p>ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).</p> <p>Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</p>		
<p>1. <input checked="" type="checkbox"/> A Notice of Appeal was filed on <u>09 July 2002</u>. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.</p> <p>2. <input checked="" type="checkbox"/> The proposed amendment(s) will not be entered because:</p> <p>(a) <input checked="" type="checkbox"/> they raise new issues that would require further consideration and/or search (see NOTE below);</p> <p>(b) <input type="checkbox"/> they raise the issue of new matter (see Note below);</p> <p>(c) <input checked="" type="checkbox"/> they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or</p> <p>(d) <input type="checkbox"/> they present additional claims without canceling a corresponding number of finally rejected claims.</p> <p>NOTE: <u>see attached</u>.</p> <p>3. <input type="checkbox"/> Applicant's reply has overcome the following rejection(s): _____.</p> <p>4. <input type="checkbox"/> Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).</p> <p>5. <input checked="" type="checkbox"/> The a)<input type="checkbox"/> affidavit, b)<input type="checkbox"/> exhibit, or c)<input checked="" type="checkbox"/> request for reconsideration has been considered but does NOT place the application in condition for allowance because: <u>see attached</u>.</p> <p>6. <input type="checkbox"/> The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.</p> <p>7. <input checked="" type="checkbox"/> For purposes of Appeal, the proposed amendment(s) a)<input checked="" type="checkbox"/> will not be entered or b)<input type="checkbox"/> will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.</p> <p>The status of the claim(s) is (or will be) as follows:</p> <p>Claim(s) allowed: <u>NONE</u>.</p> <p>Claim(s) objected to: <u>NONE</u>.</p> <p>Claim(s) rejected: <u>1-9</u>.</p> <p>Claim(s) withdrawn from consideration: <u>NONE</u>.</p> <p>8. <input type="checkbox"/> The proposed drawing correction filed on _____ is a)<input type="checkbox"/> approved or b)<input type="checkbox"/> disapproved by the Examiner.</p> <p>9. <input type="checkbox"/> Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.</p> <p>10. <input type="checkbox"/> Other: _____</p> <p style="text-align: center;"><i>Christopher L. Chin</i> CHRISTOPHER L. CHIN PRIMARY EXAMINER GROUP 1800/641</p> <p style="text-align: right;"><i>Gailene R. Gabel</i> 8/27/02</p>		

Supplemental Advisory Action

1. The After Final amendment of claim 2 attempts to correct pending indefiniteness issues, originally set forth in the first Office Action, Paper No. 7, and maintained in the final Office Action, Paper No. 9. The indefiniteness issue involves lack of essential method steps, i.e. correlation step, which is necessary for consistency to meet the requirement of the preamble in claim 2.

The rejection of claim 2 under 35 USC 112, second paragraph was originally traversed by Applicant in response to the first Office Action in Paper No. 8, and rendered without merit by Applicant, for reason that the claim is clear and proper if read in light of the specification upon which Applicant pointed to page 6, lines 16-24 for support. Further, there was no amendment set forth for claim 2 at that time, to either correct or otherwise clarify the claim so as to overcome the rejection set forth in the first Office Action.

Accordingly, the 35 USC 112, second paragraph rejection of claim 2 was maintained in the final Office Action in Paper No. 9, as being indefinite and unclear for reason that although claim 2 is interpreted in light of the specification, limitations from the specification cannot be read into the claim. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Specifically, claims in an application for an invention should stand on their own merit. At final Office Action, the prosecution was closed.

2. Addressing item nos. 2 and 5 of the Advisory Action, the amendment of claim 2 raises new issues requiring further consideration under the provisions of 35 USC 112, second paragraph as follows:

- In step 3), the recitation of “which beads bind any radiolabeled peptidoglycan synthesized” is vague and indefinite because it fails to clearly define what element, i.e. lectin, of the bead binds. By such recitation, the claim encompasses non-specific binding by the beads to other components, which does not appear to be Applicant’s intent. Further, the recitation of “radiolabeled peptidoglycan” lacks clear antecedent support in step 1) because in step 1), the “UDP-N-acetyl glucosamine” is radiolabeled.
- In step 4), the recitation of “measuring light energy emitted by the fluorescer, which is indicative of the presence of radiolabeled peptidoglycan synthesized in step 1” is ambiguous because it appears that the recited “lectin-coated beads impregnated with a fluorescer” recited in step 3) emit light energy, whether they are bound or unbound, and there is no separation therebetween to distinctly define between light energy emitted by unbound lectin-coated beads and those that bound to the supposed synthesized peptidoglycan; therefore, it is unclear and/or not clearly defined, how the step of “measuring light energy emitted by the fluorescer” excludes non-specific autofluorescence from the unbound lectin-coated beads impregnated with a fluorescer.

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3. Accordingly, the claims are not in condition for allowance and the issues have not been simplified so as to be in better form for appeal.

4. For the record, Applicant's request for reconsideration and amendment entry in the telephonic interview on 8/27/02 has been considered but is not persuasive.

Interview Summary	Application No.	Applicant(s)	
	09/341,196	DESOUSA ET AL.	
	Examiner Gailene R. Gabel	Art Unit 1641	

All participants (applicant, applicant's representative, PTO personnel):

(1) Gailene R. Gabel. (3)_____.

(2) Mr. Sterner. (4)_____.

Date of Interview: 27 August 2002.

Type: a) Telephonic b) Video Conference
c) Personal [copy given to: 1) applicant 2) applicant's representative]

Exhibit shown or demonstration conducted: d) Yes e) No.
If Yes, brief description: _____.

Claim(s) discussed: of record.

Identification of prior art discussed: of record.

Agreement with respect to the claims f) was reached. g) was not reached. h) N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i) It is not necessary for applicant to provide a separate record of the substance of the interview(if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case unless both applicant and examiner agree that the examiner will record same. Where the examiner agrees to record the substance of the interview, or when it is adequately recorded on the Form or in an attachment to the Form, the examiner should check the appropriate box at the bottom of the Form which informs the applicant that the submission of a separate record of the substance of the interview as a supplement to the Form is not required.

It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner.
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicant questioned the non-entry of claim amendments after final rejection and contends that the information incorporated therein was obtained from and supported by the specification, and was intended only to clarify and correct pending 35 USC 112, second paragraph issues; thus, the amendment should not require further consideration and search for evaluation of patentability. Indicated to Applicant that Examiner will further consider the amendment in light of Applicant's argument in the interview and will discuss the issues with a Primary Examiner as necessary. Accordingly, a supplemental Advisory Action is being issued to Applicant.